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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,879	07/21/2006	Masako Nakazawa	293592US0PCT	8110

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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	**PAPER NUMBER**
1614	

NOTIFICATION DATE	DELIVERY MODE
01/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/586,879	NAKAZAWA ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1 sheet, 7/21/2006; 4 sheets, 10/18/2006; 1 sheet, 4/5/2008; 1 sheet, 6/3/2008.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1 and 4-5, and the specie sodium sulfite in the reply filed on 11/7/2008 is acknowledged. Applicant's traversal is persuasive and claim 2 has been rejoined and is currently under examination.

Claims 1-5 are pending in the application. Accordingly, claim 3 has been deleted, claims 1-2 and 4 have been amended, no claims are newly added.

This application is the national stage entry of PCT/JP2005/001902 filed 2/9/2005; and claims benefit of foreign priority document JAPAN 2004-035985 filed 2/13/2004 and foreign priority document JAPAN 2004-035986 filed 2/13/2004.

Claims 1-2 and 4-5 are currently under examination and the subject of this Office Action.

Information Disclosure Statement

The information disclosure statements filed on 7/21/2006; 10/18/2006; 4/5/2006 and 6/3/2008 have been received. Documents with no publication date were not considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Ahmad et al (US 2006/0030578).

Ahmad et al. teach of a method of making SN38 or irinotecan complexes comprising formulating dehydrated or lyophilized complexes containing liposomes and SN38, irinotecan or compounds in equilibrium with SN38 or irinotecan respectively, dissolving or resuspending the dehydrated or lyophilized complexes in an aqueous solution, and contacting the liposomes with an activating agents such that SN38 or irinotecan becomes active. The activating agent can be any acidic aqueous buffer such as sodium acetate or acetic acid (paragraph [0028]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (U.S. 2003/0211180 in view of Ahmad et al (U.S. 2006/0030578).

Cheng et al. teach of an internal standard solution consisting of irinotecan with acetonitrile and glacial acetic acid (paragraph [0266]). Further it is taught that irinotecan exhibits anti-tumor activity in cancer patients (paragraph [0101]).

Ahmad et al. teach that sodium acetate and acetic acid are both acidic aqueous buffers.

It would have been prima facie obvious to one of ordinary skill in the art to substitute the glacial acetic acid of Ahmad et al for the acetic acid in the composition of Cheng et al because both sodium acetate and acetic acid are functional equivalents (i.e. acidic buffering agents), one of ordinary skill in the art would have been motivated to substitute the glacial acetic acid per Cheng et al. with sodium acetate and expect the composition to have similar activity.

The determination of the optimum pH of the claimed liquid dosage form would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (U.S. 2003/0211180 in view of Ahmad et al (U.S. 2006/0030578) as applied to claims 1 and 4-5 above, and further in view of Chen et al (U.S. 6,383,471).

The combination of Cheng et al (U.S. 2003/0211180 in view of Ahmad et al (U.S. 2006/0030578) as evidenced by MeSH Supplementary Concept Data (2008) is set forth supra. The combination differs by not comprising component (C) of claim 2.

Chen et al teach of a composition suitable for use in oral dosage (abstract). A therapeutic agent taught is irinotecan (claim 12). The solubilizer of the instant invention includes propylene glycol and cyclodextrin (column 3). Suitable bases include acetic acid and ascorbic acid (column 11).

It would have been *prima facie* obvious to the skilled artisan at the time the invention was made to additionally add the instantly claimed solubilizers and bases to form the instant composition because it is known in the prior art that this composition is suitable for use in oral dosage.

Relevant Cited Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. MeSH Supplementary Concept data (2008) is cited to show that CPT-11 is a laboratory designation for irinotecan.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645